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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/204,238 12/03/98 HAMILTON G AR138-X

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HM12/1207

EXAMINER

CHANG, C

ART UNIT

PAPER NUMBER

1612

13

DATE MAILED:

12/07/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademark**

# Office Action Summary

Application No.  
**09/204,238**

Applicant(s)

**Hamilton et al.**

Examiner

**Celia Chang**

Group Art Unit

**1612**



☒ Responsive to communication(s) filed on Nov 8, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-71 is/are pending in the application.

Of the above, claim(s) 12, 13, and 26-71 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-11 and 14-25 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4-6, 8-10

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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#### DETAILED ACTION

1. Applicant's election with traverse of group I, claim 5 wherein  $n=1$  five membered ring compounds, with (2S)-1-(3,3-dimethyl-1,2-dioxopropyl)-2-(3-thiazolidine)carboxylic acid as the elected species in Paper No.12, dated October 8, 1999 is acknowledged. The traversal is on the grounds that there is no serious burden to search the Markush claims. This is not found persuasive because the reason for restriction is that the claims are drawn to independent and patentably distinct compounds which differ in elements, bonding arrangements and chemical properties to such an extent that a reference anticipates a compound would not render another compound in the same obvious. It is noted that the compounds being provisoed out at the end of claim 1 and a structural delineation of these compounds attached to paper No.10 dated Oct. 21, 1999 have structural diversified rings for independent and distinct uses e.g.:

CA 120:323484, L4-6 membered ring compounds as angiotensin II receptor antagonists;

CA 105:133909, L1-six membered ring as antihypertensives;

CA 122:314456, L3-thiazoxolidines as intermediates for making anti-inflammatory;

CA 97:88995, L3-thiazoxolidines as metalloproteinase inhibitors;

CA 76:140885, L3-oxazolidines as antidepressants;

CA 76:99688 L1-thiazoxolidines as intermediates for making cephalosporin;

CA 93:168254, L4-thiaoxalidines as antibacterial.

It is evidenced that not only the different size rings are structural material for distinct utility, but also the A moieties being drawn to the different structure are independent material for identifiable diversified utilities.

In the event that applicant's traversal is also on the ground that the species are not patentably distinct, applicant did not submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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If such identification or admission were made, then there could have been no patentability of all the inventions over Yoshida et al. US 4,510,154 (see col. 15-16 compounds 50, 52 anticipated the claims when the heterocyclic ring is substituted, A is L4, R2 is carboxylic isostere triazole, i.e. CA 115:92147).

According to MPEP 803.02 restriction for Markush claims, broadly, unity of invention exists where compounds included within a Markush group (i) share a common utility and (ii) share a substantial structural feature disclosed as being essential to that utility. From the above evidenced provided by applicants proviso out from the claims, no common core essential to the claimed utility can be found for the Markush claims.

Based on the election of group I and the species of (2S)-1-(3,3-dimethyl-1,2-dioxopropyl)-2-(3-thiazolidine)carboxylic acid, the subject matter being examined is limited to n=1, A=L1 compounds. Claims 1-11 reading on the elected compounds are examined together with claims 14-25 limited to treating Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis. Claims 12-13, 26-71 and the remaining compounds or method of claims 1-11, 14-25 are withdrawn from consideration per 37 CFR 1.142(b).

The requirement is still deemed proper and is therefore made FINAL.

2. An enormous number of prior art references have been submitted without description of relevancy. These references as cited on the 1449 have been given a **cursory** review commensurate to the manner they are submitted.
3. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Confusion that claims 1-11 failed to correspond in scope with that which applicant(s) regard as the invention can be found in the inconsistency among the claims. Please note that

I) in claim 1, the R2 moiety is a carboxylic acid or a carboxylic acid isostere.

While ester of a carboxylic acid is considered an "isostere", an

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hydroxy/hydroxyalkyl group has not been recognized in the art as such an isostere;

ii) in claim 2, the R2 moiety was limited to cyclic structures containing CH<sub>2</sub>, O, S, or N, while those disclosed in p.8 (or claim 3) do not contain such structure (please note that none of the structure in p.8 has a CH<sub>2</sub> node nor does the descriptive scope of R3 substituents include oxo;

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Henery-Logan CA 79:31977, or Andrew CA 128:114889, or Dunkerton CA 94:84059, see structural delineation of compounds attached.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henery-Logan CA 79:31977, or Andrew CA 128:114889, or Dunkerton CA 94:84059.

Henery-Logan CA 79:31977, or Andrew CA 128:114889, or Dunkerton CA 94:84059 disclosed compounds anticipated the base claim. The difference between the claims i.e. the elected species and the prior art is in the addition of additional straight or branched alkyl chain. The variation of chain length is normally not patentable in absence of unexpected results because to those skilled in chemical art one homologue is not such an advance over adjacent member of

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series as requires invention unless beneficial properties realized in new homologue lie clearly outside of expectation. In re Wood 199 USPQ 137; In re Iohr 137 USPQ 548; In re Hoke 195 USPQ 148; In re Fauque 121 USPQ 425.

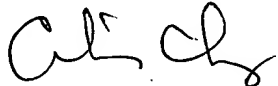
6. Claims 1-11 and 14-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,801,187. Although the conflicting claims are not identical, they are not patentably distinct from each other because to the extent that carboxylic isosteres included carboxylic ester, overlapping subject matter are claimed. To the extent that the carboxylic acid isosteres are drawn to those art recognized prima facie obvious variations of the isosteres, claims 1-11, 14-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,801,187 in view of EP 400,974. The difference between the compounds of the instant claims and those of Li et al. '187 is the replacement of one carboxylic acid isostere with another conventional known isostere (see EP400974, p.2-3 isosteres of carboxylic acids). The term "isostere" is the equivalency of carboxylic acid moiety. Employing one equivalence in place of another is the conventional skill of isosterism. There is nothing unobvious in employing the well documented skill of the art with the exact expectation of the skill of isosterism.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is (703) 308-4702.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

CCC/Chang

Nov. 29, 1999

  
CEILA CHANG  
PRIMARY EXAMINER  
GROUP 1200 1612